

4/29/99

K991092

510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EBI SpineLink™ Anterior Cervical Spinal System is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** Electro-Biology, Inc. **Contact Person:** Jon Caparotta
100 Interpace Parkway Telephone: (973) 299-9022
Parsippany, NJ 07054

Date prepared: March 30, 1999

2. **Proprietary Name:** EBI SpineLink™ Anterior Cervical Spinal System
Common Name: Spinal Fixation Device
Classification Names: Spinal Intervertebral Body Fixation Orthosis

3. **Predicate or legally marketed devices that are substantially equivalent:**

- EBI SpineLink™ Anterior Cervical Spinal System
- Synthes® Cervical Spine Locking Plate

4. **Description of the device:** The EBI SpineLink™ System is a cervical spinal fixation device that uses interconnecting links. This submission is for the addition of a 4.5mm diameter bone anchor screw.

5. **Intended Use:** The EBI SpineLink™ Anterior Cervical Spinal System is intended for anterior interbody screw fixation of the cervical spine at levels C3-C7. The System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions.

Warning: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

6. **Materials:** The components of the system are manufactured from Ti-6Al-4V ELI per ASTM F136.

- 7. Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the EBI SpineLink™ Anterior Cervical Spinal System and other currently marketed spinal systems. It is substantially equivalent* to the predicate devices in regards to intended use, materials and function. Testing comparing the modifications to the previous system demonstrated that the device complies with applicable standards and meets all of its functional requirements.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Pre-market Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 1999

Mr. Jon Caparotta
Manager, Regulatory Affairs
Electro-Biology, Inc.
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K991092
Trade Name: EBI SpineLink™ Anterior
Cervical Spinal System
Regulatory Class: II
Product Code: KWQ
Dated: March 29, 1999
Received: April 1, 1999

Dear Mr. Caparotta:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

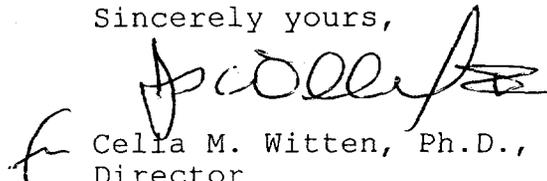
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



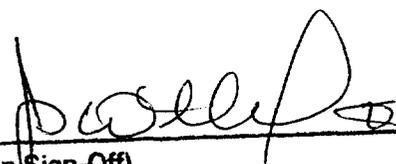
Cella M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use:

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WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 12991092

Prescription Use X
(Per 21 CFR 801.109)